

## Remarks

### Rejections Under 35 U.S.C. § 103(a)

Claims 9, 10, 24-29, 33, 39, 40, 42, 43, 49-52, 54-60, 63-66, and 68-75 stand rejected as obvious over Shiver (WO 98/34640), Haas (Current Biology 1996 6:315-324), Persson (Biologicals 1998 26:255-65) and Novitsky (Genbank Accession Nos. AF110965 and AF110967).<sup>1</sup> The Office Action adds March (U.S. Pat. No. 5,797,870) to these references to reject claim 53 and adds Kapitonov (U.S. Pat. No. 6,280,989) to reject claims 30-32 and 34-38. Office Action at pages 7-9. Applicants traverse the rejection.

The Patent Office cites Novitsky as disclosing wild type HIV *gag* sequences and contends that it would have been obvious to modify the Novitsky sequences “by altering the codon-usage of the sequence and by removing the INS elements, as taught by Shiver, *et al.* and Haas, *et al.*” Office Action at page 6.

To establish a *prima facie* case of obviousness, an examiner must make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003), *citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Moreover, as the Supreme Court recently stated, “*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), *citing In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added).

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<sup>1</sup> The rejection refers to “claims 42-52,” but claims 44-48 are canceled.

The Office Action does not establish a *prima facie* case of obviousness for any of the rejected claims because none of the references, alone or in combination, teaches or suggests all elements of the claims. Independent claims 68 and 69 recite modified *gag* sequences SEQ ID NOS:3 and 4. Specification at page 26 ¶ 2 to page 27 ¶ 2. The recited *gag* sequences are modified for human codon usage and to remove INS sequences. The cited references do not teach or suggest these sequences and, moreover, none of the cited references alone or in combination provides any reason, teaching, or suggestion to remove the INS sequences from a wild-type *gag* coding sequence. INS sequences are present in the wild-type *gag* sequences, not generated by codon replacements. Shiver teaches replacing wild-type codons with “an optimal codon for high expression in human cells” (page 28, line 15) and “inspecting the new gene for undesired sequences generated by these codon replacements” (page 28, lines 18-19). But Shiver does not teach or suggest removing INS sequences. Rather, Shiver teaches checking the newly created sequence for “inadvertently” created sequences such as intron splice recognition sites and unwanted restriction enzyme sites.

Neither Haas nor Perrson cures the defect of Shiver. Like Shiver, Haas teaches codon optimization. Perrson is cited as teaching viral vectors in which the reverse transcriptase- and integrase-encoding sequences of the HIV *pol* gene are deleted, which is not relevant to deletion of INS sequences. Because none of the references, alone or in combination, provides any reason, suggestion, or teaching to modify the wild-type *gag* sequences by removing an INS sequence, neither independent claims 68 and 69 nor dependent claims 9, 10, 24-29, 33, 39, 40, 42, 43, 49-52, 54-60, 63-66, and 70-75 are *prima facie* obvious over the combination of Shriver, Haas, Persson, and Novitsky.

March was combined with Shiver, Haas, Perrson and Novitsky to reject dependent claim 53. Kapitonov was combined with Shiver, Haas, Perrson and Novitsky to reject claims 30-32 and 34-38. March is cited as teaching the use of Sindbis viral vectors. Kapitonov is cited as teaching a variety of host cells for expression vectors. Neither reference provides any reason, suggestion, or teaching to remove an INS sequence from a *gag* coding sequence, and therefore neither reference cures the deficiencies of the combination of Shiver, Haas, Perrson and Novitsky. Thus, claims 30-32, 34-48 and 53 are not *prima facie* obvious over the cited combinations of references.

Please withdraw the rejections.

Respectfully submitted,

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